

Annex

**Nicotine in Cigarettes and Smokeless Tobacco
Is a Drug and These Products Are Nicotine Delivery Devices
Under the Federal Food, Drug, and Cosmetic Act:
Jurisdictional Determination**

August 1996



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

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EXECUTIVE SUMMARY

This document explains the basis for the Food and Drug Administration's assertion of jurisdiction over cigarettes and smokeless tobacco under the Federal Food, Drug, and Cosmetic Act (the Act). FDA regulates a diverse range of products under the Act, including foods, drugs, medical devices, and cosmetics. The distinguishing feature that characterizes these products is their intimate and potentially harmful relationship with the human body. The products that FDA regulates include those that are ingested, inhaled, implanted, or otherwise used in close contact with the human body.

Cigarettes, which deliver a pharmacologically active dose of nicotine to the body through inhalation, and smokeless tobacco, which delivers a pharmacologically active dose of nicotine to the body through buccal absorption, share this distinguishing feature. Like the products that FDA traditionally regulates, cigarettes and smokeless tobacco are inhaled or placed within the human body; like many of these products, they deliver a pharmacologically active substance to the bloodstream; and like these products, they have potentially dangerous effects. Indeed, no products cause more death and disease than cigarettes and smokeless tobacco.

FDA is asserting jurisdiction over cigarettes and smokeless tobacco under the drug and device provisions of the Act. Specifically, FDA has concluded that cigarettes and smokeless tobacco are combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body. FDA last considered whether cigarettes were drugs or devices in the late 1970's. *See Action on Smoking and Health v. Harris*,